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09/485,845 04/26/00 FUNAMIZU

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HM12/0710

EXAMINER

COLEMAN, R

ART UNIT

PAPER NUMBER

1624

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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# Office Action Summary

Application No.  
**09/485,845**

Applicant(s)  
**FUNAMIZU et al.**

Examiner  
**Brenda Coleman**

Art Unit  
**1624**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 30, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above, claim(s) 26-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1 & 6
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 1-32 are pending in the application.

#### *Election/Restriction*

1. Applicant's election of Group I in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 26-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected subject matter. Election was made **without** traverse in Paper No. 8.
3. Claims 1-25 are rejected as being drawn to an improper Markush group. The recited compounds, while possessing a common utility, differ widely in structure and are not art-recognized equivalents and are thus, independently distinct for the reasons set forth in the restriction requirement. The Markush group represented by the terms A, B and D have variably different definitions, rendering the claims clearly improper.

#### *Priority*

4. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title

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a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/US98/17232, filed August 20, 1998 which is a (divisional, continuation or continuation-in-part) of application Serial Number 08/916,575, filed August 22, 1997 now abandoned.” is suggested.

### *Specification*

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). **An abstract on a separate sheet is required.**

7. The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179

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USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

8. The disclosure is objected to because of the following informalities: pages 4, 11, 18, 25, 32, 39, 46, 53, 60 and 67 as well as claims on pages 74, 81 and 88 are not legible in that there is what appears to be a smear of the text spanning the left hand side of each page. The claims have been examined to the extent in which they could be read.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 18-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of the method claims are not adequately enabled solely based on growth hormone releasing factor provided in the specification. Instant claim language embraces disorders not only for treatment but for **prevention** which is not remotely enabled. It is presumed in the prevention of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop a osteoporosis, immune deficiency, obesity, etc. There is no evidence of

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record which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disorders claimed herein.

10. Claims 1-4, 6-14 and 16-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In evaluating the enablement question, several factors are to be considered. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988); *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace a wide range of chemically and physically distinct compounds, wherein A and B are lipophilic groups and D is a group having at least one amino or substituted amino group. The specification states that twenty four compounds where A is benzothiazepine, benzoazepine, benzoxazepine, phenothiazine, benzoazocines, benzothiazine, dibenzoxazepine and dibenzoazocine, which is insufficient to support the breadth of the claims. Examples should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure. Markush claims are subject to rejection based upon the lack of supporting disclosure when the “working

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examples” fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear, and exact terms. See *In re Fouche* 169 USPQ 429. The compounds tested are not seen as adequately representative of the compounds encompassed by the extensive Markush groups instantly claimed for the uses instantly asserted and claimed.

11. Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following reasons apply:

- a) There is no definition in the specification for the myriad of possible aromatic compounds claimed herein. The aromatic moiety which is defined for the substituent A<sup>1</sup> in the claims is opened ended and reads on all such rings and ring systems of which are neither supported nor contemplated. *In re Lund* 153 USPQ 625.
- b) There is no definition in the specification for “aryl” which is open ended. The instant claim language indicates that “aryl” includes phenyl, naphthyl as well as hetero rings of which are neither supported nor contemplated. *In re Lund* 153 USPQ 625. See *In re Surrey* 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-14 and 16-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

- a) Claims 1-4, 6-14 and 16-25 are vague and indefinite in that it is not known what is meant by the definition of A and B which is open ended in that the definition of "A and B are a lipophilic group" does not define the possible limitations of the compounds as claimed.
- b) Claims 1-4, 6, 7 and 16-25 are vague and indefinite in that it is not known what is meant by the definition of D where "substituted" appears, e.g. substituted amino group. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.
- c) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of M<sup>1</sup> where "substituted" appears, e.g. substituted or unsubstituted alkylene. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.
- d) Claim 3 is vague and indefinite in that it is not known what is meant by the definition of the substituents of A<sup>2</sup> where "substituted" appears several times, e.g. substituted alkyl, substituted cycloalkyl, substituted alkoxy, substituted sulfonyl,



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etc. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.

- e) Claim 3 is vague and indefinite in that it is not known what is meant by "sulfonyl,substituted sulfenyl" in line 21 and "substitutedamino" in line 22 of page 74. It is believed that a space is needed.
- f) Claim 3 is vague and indefinite in that the definition of M<sup>1</sup> states "and / or" which indicates that the substituents of M<sup>1</sup> can be halogen, hydroxy, (C<sub>1</sub>-C<sub>5</sub>)alkyl and (C<sub>1</sub>-C<sub>5</sub>)alkoxy at the same time.
- g) Claim 4 is vague and indefinite in that it is not known what is meant by "(C<sub>1</sub>-C<sub>5</sub>)alkoxy,(C<sub>1</sub>-C<sub>5</sub>)perfluoralkyl" in line 5 of page 75. It is believed that a space is needed.
- h) Claim 4 is vague and indefinite in that it is not known what is meant by the definition of the substituents of A<sup>3</sup> and A<sup>4</sup> and the definition of Z where "substituted" appears several times, e.g. substituted sufonyl, substituted sulfenyl, substituted sulfinyl, substituted amino, etc. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.
- i) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety "sufonyl" in the definition of A<sup>3</sup>. It is believed that the moiety should be sulfonyl. See line 6 on page 75.

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- j) Claim 4 is vague and indefinite in that the definition of the substituents of A<sup>3</sup> states “and / or” which indicates that the substituents of A<sup>3</sup> can be halogen, hydroxy, (C<sub>1</sub>-C<sub>5</sub>)alkyl, (C<sub>1</sub>-C<sub>5</sub>)alkoxy, etc. at the same time.
- k) Claim 4 recites the limitation “-S(O)<sub>r</sub>-, -C(O)-, -C(S)-” in definition of X. There is insufficient antecedent basis for this limitation in the claim. The list of substituents in claim 3 for A<sup>2</sup> does not include =O or =S.
- l) Claim 4 recites the limitation “-C(O)-, -C(S)-” in definition of Y. There is insufficient antecedent basis for this limitation in the claim. The list of substituents in claim 3 for A<sup>2</sup> does not include =O or =S.
- m) Claim 4 is vague and indefinite in that it is unclear how Z by itself forms the fused ring A<sup>4</sup>.
- n) Claim 4 is vague and indefinite in that the definition of the substituents of A<sup>4</sup> states “and / or” which indicates that the substituents of A<sup>4</sup> can be halogen, hydroxy, (C<sub>1</sub>-C<sub>5</sub>)alkyl, (C<sub>1</sub>-C<sub>5</sub>)alkoxy, etc. at the same time.
- o) Claim 5 is vague and indefinite in that it is not known what is meant by “Claim4” in line 13 of page 76. It is believed that a space is needed.
- p) Claim 6 is vague and indefinite in that it is not known what is meant by “Claim1” in line 35 of page 76. It is believed that a space is needed.
- q) Claims 6 and 7 are vague and indefinite in that it is not known what is meant by the definition of B where “substituted” appears several times, e.g. substituted alkyl,

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substituted cycloalkyl, etc. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.

- r) Claim 7 is vague and indefinite in that it is not known what is meant by "Claim6" in line 39 of page 76. It is believed that a space is needed.
- s) Claim 7 recites the limitation "indolylalkyl and quinolylalkyl" in definition of B. There is insufficient antecedent basis for this limitation in the claim.
- t) Claim 8 is vague and indefinite in that it is not known what is meant by "Claim1" in line 6 of page 77. It is believed that a space is needed.
- u) Claim 8 is vague and indefinite in that it is not known what is meant by the definition of the  $R^1$ ,  $R^2$ ,  $R^3$ ,  $R^5$ ,  $R^6$ ,  $R^7$ ,  $R^8$ ,  $R^9$  and  $R^{10}$  where "substituted" appears several times, e.g. substituted alkyl or substituted cycloalkyl. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.
- v) Claim 8 is vague and indefinite in that the definition of  $R^2$  and  $R^3$  can be taken together to form alkylene is unclear, since  $R^2$  and  $R^3$  are both attached to a nitrogen atom. Any cyclization with  $R^2$  and  $R^3$  would always form a heterocycle.
- w) Claim 8 is vague and indefinite in that the definition of  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  can be taken together with  $R^1$  or  $R^2$  to form an alkylene is unclear, since  $R^1$  and  $R^2$  are both attached to a nitrogen atom. Any cyclization with  $R^5$ ,  $R^6$ ,  $R^7$  and  $R^8$  would always form a heterocycle.

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- x) Claim 8 is vague and indefinite in that it is not known what is meant by “R<sup>8</sup>are” in line 14 of page 77. It is believed that a space is needed.
- y) Claim 8 is vague and indefinite in that it is not known what is meant by “-C(O)OR<sup>9</sup>,” such that there are two commas following the moiety. It is not known if a moiety is missing or not.
- z) Claim 8 is vague and indefinite in that it is not known what is meant by “orR<sup>2</sup>” in line 16 of page 77. It is believed that a space is needed.
- aa) Claim 8 is vague and indefinite in that the definition of R<sup>5</sup> and R<sup>7</sup> or R<sup>6</sup> and R<sup>8</sup> can be taken together to form alkylene or heterocycle is unclear, since there would be no hetero atom present in cyclization.
- ab) Claim 8 is vague and indefinite in that it is not known what is meant by “andR<sup>7</sup>or” or “andR<sup>8</sup>can” in line 19 of page 77. It is believed that a space is needed.
- ac) Claim 8 is vague and indefinite in that it is not known what is meant by “R<sup>5</sup>and” or “R<sup>8</sup>can” in line 20 of page 77. It is believed that a space is needed.
- ad) Claim 8 is vague and indefinite in that it is not known what is meant by “R<sup>5</sup>and” in line 21 of page 77. It is believed that a space is needed.
- ae) Claim 9 is vague and indefinite in that it states that “wherein D is”, however there is no definition for D.
- af) Claim 9 is vague and indefinite in that it is not known what is meant by the definition of the R<sup>2</sup>, R<sup>3</sup>, R<sup>5</sup>, R<sup>6</sup>, R<sup>7</sup> and R<sup>8</sup> where “substituted” appears several

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times, e.g. substituted (C<sub>1</sub>-C<sub>5</sub>)alkyl. "Substituted" without reciting intended substituents renders the claim unclear and indefinite as to number and nature of substitution.

- ag) Claim 10 is vague and indefinite in that it is not known what is meant by "Claim9" in line 14 of page 78. It is believed that a space is needed.
- ah) Claim 10 does not end in a period.
- ai) Claim 17 is a substantial duplicate of claim 16, as the only difference is a statement of intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.
- aj) Claims 17 and 21 are vague and indefinite as to the nature of the composition which includes "said growth hormone". Which growth hormone?
- ak) Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
- al) Claim 25 does not end in a period.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 6, 7, 16 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Collins et al., U.S. Patent Number 5,441,950 and Chandrakumar et al., U.S. Patent Number 5,449,675. U.S. '950 and U.S. '675 teach compounds of the instant invention where A is dibenzoxazepine, R is hydrogen, B is hydrogen or methyl and D is 4-pyridinylmethylamino, 2-pyridinylethylamino, 4-pyridinylamino or 2-methoxymethylamino. See examples 5-8, 15, 16, 35-38 and 41-42.

14. Claims 1-7, 16 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al., EP 0 411 751. EP '751 teaches the compounds of the instant invention where A is benzothiazepine-ethyl, R is hydrogen, B is phenylmethyl and D is -NH-CH(isobutyl)-C(=O)-NH-CH(cyclohexylmethyl)-CH(OH)-CH<sub>2</sub>-C(=O)-NH-(CH<sub>2</sub>)<sub>3</sub>-imidazole. See examples E18, E19a and E19b.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. Claims 1, 6-10, 16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandrakumar et al., U.S. Patent Number 5,449,675. The generic structure of U.S. '675 encompasses the instantly claimed compounds (see Formula I, column 2) and by the same process (see column 11) as claimed herein. Examples 5-8, 15, 16, 35-38 and 41-42 differ only in the nature of the X, Y, Z, R, W, D, E, m, p, q and n substituents. Column 2, line 57 through column 3, line 15 defines the substituent X and Y as hydrogen, halogen or alkyl; Z is oxygen, sulfur, -S(=O)- or -S(=O)(=O)-; R is hydrogen or alkyl, W is hydrogen or alkyl; D is aryl, -NR<sup>1</sup>-C(=O)-, -NR<sup>1</sup>-C(=O)-O-, -C(=O)-, -C(=O)-O- or -C(=O)-NR<sup>1</sup>-; R<sup>1</sup> is hydrogen, alkyl, hydroxy or alkoxy; E is hydrogen, alkyl, aryl, alkylaryl, -NRR or -alkylene-NRR; m is an integer of from 0 to 8; p is 0 or 1; q is an integer from 0 to 8; and n is 0 or 1. Compounds of the instant invention are generically embraced by U.S. '675 in view of the interchange ability of the X, Y, Z, R, W, D, E, m, p, q and n substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example dibenzothiazepine or dibenzothiazepin-1-one as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

16. Claims 1, 6-10, 16 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al., EP 0 411 751. The generic structure of EP '751 encompasses the instantly claimed compounds (see Formula I, page 3) and by the same process (see pages 8-9) as claimed herein.

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Examples E18, E19a and E19b differ only in the nature of the  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$ ,  $Z_5$ ,  $R_a$ ,  $R_b$ ,  $E$ ,  $R_1$ ,  $R_2$ ,  $R_3$ ,  $p$ ,  $R_z$ ,  $q$ ,  $A$ ,  $s$  and  $R_4$  substituents. Page 3, line 36 through page 4, line 3 defines the substituent  $Z_1$  is absent and  $Z_2$ ,  $Z_3$ ,  $Z_4$  and  $Z_5$  and the carbon atoms to which  $Z_2$  and  $Z_5$  are attached, form a 6-membered non-aromatic heterocyclic ring; or  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$ ,  $Z_5$  and the carbon atoms to which  $Z_1$  and  $Z_5$  are attached, form a 7-membered non-aromatic heterocyclic ring;  $E$  is absent or is  $(CH_2)_n$  or  $CH(CH_2)_{n-1}$  wherein  $n$  is 1 to 4;  $A$  is  $-CONH-$ ,  $-NHCO-$ ,  $-COO-$ ,  $-S(O)_r-$  wherein  $r$  is 0, 1 or 2, or  $-CH_2-$ ;  $p$  is 0, 1 or 2;  $s$  is 0, 1, 2, 3 or 4;  $q$  is 0 or 1;  $R_z$  is hydrogen,  $C_{1-6}$  alkyl or, when  $A$  is  $-CH_2-$ , hydroxy;  $R_a$  and  $R_b$  are independently selected from hydrogen or a substituent;  $R_1$  is  $CH_2R_9$  wherein  $R_9$  is optionally substituted aryl or heteroaryl;  $R_2$  is  $CHR_{10}R_{11}$  wherein  $R_{10}$  is hydrogen or methyl and  $R_{11}$  is  $C_{1-6}$  alkyl,  $C_{3-8}$  cycloalkyl, optionally substituted aryl or heteroaryl, or  $R_{11}$  is amino,  $C_{2-7}$  alkanoylamino, 2-oxopyrrolidinyl, 2-oxopiperidinyl or  $C_{1-6}$  alkoxy-carbonylamino;  $R_3$  is  $CH_2R_{12}$  wherein  $R_{12}$  is  $C_{1-6}$  alkyl,  $C_{3-8}$  cycloalkyl or phenyl;  $R_4$  is  $C_{1-6}$  alkyl,  $C_{3-8}$  cycloalkyl, a saturated or unsaturated heterocyclic ring linked through carbon, hydroxy,  $C_{1-6}$  alkoxy,  $C_{1-7}$  alkanoyloxy, amino,  $C_{1-7}$  alkanoylamino, amino substituted by one or two  $C_{1-6}$  alkyl groups,  $C_{1-6}$  alkylsulfonyl, carboxy,  $C_{1-6}$  alkoxy-carbonyl, benzyloxycarbonyl, aminocarbonyl or  $CH-(NHR_{13})COR_{14}$  wherein  $R_{13}$  is hydrogen or  $C_{1-6}$  alkanoyl and  $R_{14}$  is hydrogen or  $C_{1-6}$  alkyl; or (when  $s$  is 2 to 4)  $R_4$  is a saturated or unsaturated heterocyclic ring linked through nitrogen.

Compounds of the instant invention are generically embraced by EP '751 in view of the interchange ability of the  $Z_1$ ,  $Z_2$ ,  $Z_3$ ,  $Z_4$ ,  $Z_5$ ,  $R_a$ ,  $R_b$ ,  $E$ ,  $R_1$ ,  $R_2$ ,  $R_3$ ,  $p$ ,  $R_z$ ,  $q$ ,  $A$ ,  $s$  and  $R_4$  substituents of the tricyclic ring system. Thus, one of ordinary skill in the art at the time the invention was



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made would have been motivated to select for example benzoxazepine, benzoazepin-1-one, benzodiazepine as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

### *Claim Objections*

17. Claims 11-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer to the claims from which they depend in the alternative. See MPEP § 608.01(n).

37 CFR 1.75. Claim(s).


(c) one or more claims may be presented in dependent form, referring back to and further limiting another claim or claims in the same application. **Any dependent claim which refers to more than one other claim (multiple dependent claim) shall refer to such other claims in the alternative only.** A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. For fee calculation purposes under § 1.16, a multiple dependent claim will be considered to be that number of claims to which direct reference is made therein. For fee calculation purposes, also, any claim depending from a multiple dependent claim will be considered to be that number of claims to which direct reference is made in that multiple dependent claim. In addition to the other filing fees, any original application which is filed with, or is amended to include, multiple dependent claims must have paid therein the fee set forth in § 1.16(d). Claims in dependent form shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Monday thru Friday from 9:00 AM to 5:30 PM.

The fax phone number for this Group is (703) 308-4734 for "unofficial" purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
Brenda Coleman  
July 9, 2001